DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Ms. Helen Redd
President
Providence Global Medical, Incorporated
4659 South, 2300 East #203
Salt Lake City, Utah 84117

DEC 17 2009

Re: K092264
Trade/Device Name: Atlantis Hyperbaric Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: November 19, 2009
Received: November 25, 2009

Dear Ms. Redd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K092264

Device Name: Atlantis Hyperbaric Ventilator

Indications for Use:

The Atlantis Hyperbaric Ventilator is indicated for use with pediatric and adult patients in respiratory failure or any other specific patient breathing requirements, as determined by the attending physician, when the patient is placed inside a hyperbaric chamber for prescribed therapy.

Prescription Use X (Part 21 C.F.R. 801 Subpart D) AND/OR Over-the -counter Use ___ (21 C.F.R. Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092264

510(k) SUMMARY

PROVIDENCE GLOBAL MEDICAL, INC.'s, ATLANTIS HYPERBARIC VENTILATOR

Submitters Name, Address, Telephone Number, Contact Person and Date Prepared

Submitters Name: Helen Redd, President
Providence Global Medical, Inc.
4659 South 2300 East, # 203
Salt Lake City, UT 84117
Telephone: 800 292 8765
Contact Person: Helen Redd, President
Date Prepared: July 15, 2009

Name of Device and Name/Address of Sponsor

Atlantis Hyperbaric Ventilator

Providence Global Medical, Inc.
4659 South 2300 East, # 203
Salt Lake City, UT 84117

Common or Usual Name

Ventilator, Continuous, Facility Use

Classification Name

Continuous Ventilator (21 C.F.R. § 868.5895)

Product Code

CBK

Predicate Device

Level-5, Inc.'s Neptune Hyperbaric Ventilator (K082351)

Indications for Use

The Atlantis Hyperbaric Ventilator is indicated for use in patients in respiratory failure or who otherwise require mechanically supported ventilation during hyperbaric therapy.

Technological Characteristics

The Atlantis Hyperbaric Ventilator consists of two main components: (1) a Control Module; and (2) a Patient Breathing Circuit. The Control Module is exterior to the hyperbaric chamber, and allows the operator to control oxygen flow to the patient. The Control Module houses pressure regulators, timing valves for control of inspiratory time, expiratory time and inspiratory flow, and pressure gauges to monitor main regulator output pressure, hyperbaric chamber pressure, and timing valve control pressure. The Patient Breathing Circuit is located inside the hyperbaric chamber, and includes an exhalation valve, a pressure relief valve, and a pressure gauge. The Patient Breathing Circuit is supplied with oxygen from the Control Module, and returns interior chamber pressure values to the Control Module. Three high-pressure hoses connect these two components through the hyperbaric chamber bulkhead. The Patient Breathing Circuit is then attached to the patient's endotracheal tube for oxygen delivery. The Control Module and the Patient Breathing Circuit are components of the Atlantis Hyperbaric Ventilator, and are supplied with the device.

Safety features include a patient airway pressure gauge, adjustable pressure relief valve, and a hand-operated oxygen flush valve.

Substantial Equivalence

The Atlantis Hyperbaric Ventilator is as safe and effective and is an exact duplicate of the predicate, designed and built by the same person as the predicate Neptune Hyperbaric Ventilator, who is now Vice-President of the Company.

The Atlantis Hyperbaric Ventilator has the same intended uses, exactly the same technological characteristics, and exactly the same principles of operations as its predicate device. Any minor technological differences between the Atlantis and its predicated device raise no new issues of safety or effectiveness. Thus, the Atlantis Hyperbaric Ventilator is substantially equivalent.